BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images, please do not report the images to the Image Problem Mailbox.

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61M 5/30 — A1

(11) International Publication Number: **WO 95/16481**

(43) International Publication Date: 22 June 1995 (22.06.95)

(21) International Application Number: PCT/HU94/00058

(22) International Filing Date: 7 December 1994 (07.12.94)

(30) Priority Data:
P 9303558 13 December 1993 (13.12.93) HU

(71) Applicant *(for all designated States except US)*: MOM INVEST KORLÁTOLT FELELŐSSÉGŰ TÁRSASÁG [HU/HU]; Mester utca 13, H-1095 Budapest (HU).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: MÁTRAI, András [HU/HU]; Marógép u. 4, H-1213 Budapest (HU). NAGY, Lajos [HU/HU]; Fodor u. 5-7, H-1126 Budapest (HU).

(74) Agent: GÖDÖLLE, KÉKES, MÉSZÁROS & SZABÓ; Keleti Károly u. 13/b, H-1024 Budapest (HU).

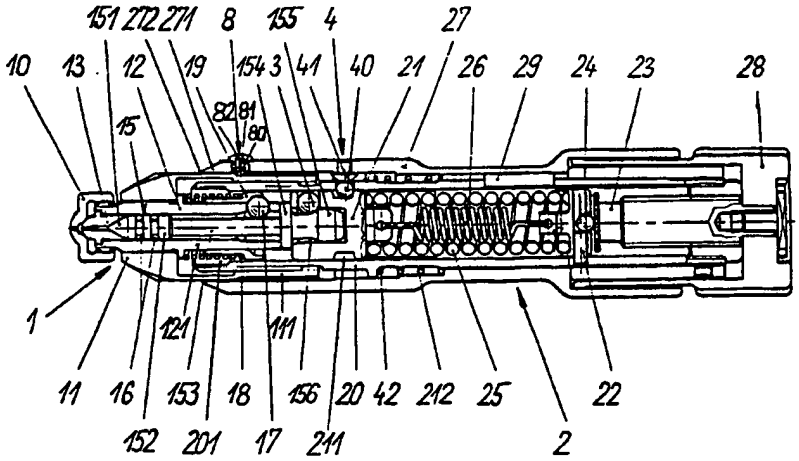
(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, ES, FI, GB, GE, JP, KE, KG, KP, KR, KZ, LK, LT, LU, LV, MD, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SI, SK, TJ, TT, UA, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD, SZ).

Published

With international search report.

Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: MEDICAL JET INJECTOR FOR ADMINISTERING INJECTIONS WITHOUT A NEEDLE



(57) Abstract

An improved medical jet injector for administering intramuscular and subcutaneous injections without a needle that includes an injection head (1) comprising a centrally located longitudinal chamber (14) capable of being filled with a determined dose of a liquid medicinal substance and a piston (15) guided to move inside said longitudinal chamber (14) and intended both to fill said chamber with the predetermined dose of the medicinal substance and to expel said substance through fine holes of a mouthpiece (10) of said injection head (1) when applied to the skin of a patient. The medical jet injector also includes an injector power unit (2) having an energy storing compression spring (25) and a releasable spring compression latch mechanism (4). The injector power unit (2) comprises a ram (21) that is slideably mounted in an inner barrel (20) and is, in normal operation of the medical jet injector, connected to the piston (15) of the injection head (1) for synchronous longitudinal movement in both directions. The injection head (1) is designed and shaped so that it forms a complete, interchangeable sub-assembly capable of being, especially for the purposes of cleaning, disinfection and/or other maintenance operations, separated as a whole from the injector power unit (2).

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgystan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo			SE	Sweden
CH	Switzerland	KR	Republic of Korea	SI	Slovenia
CI	Côte d'Ivoire	KZ	Kazakhstan	SK	Slovakia
CM	Cameroon	LI	Liechtenstein	SN	Senegal
CN	China	LK	Sri Lanka	TD	Chad
CS	Czechoslovakia	LU	Luxembourg	TG	Togo
CZ	Czech Republic	LV	Latvia	TJ	Tajikistan
DE	Germany	MC	Monaco	TT	Trinidad and Tobago
DK	Denmark	MD	Republic of Moldova	UA	Ukraine
ES	Spain	MG	Madagascar	US	United States of America
FI	Finland	ML	Mali	UZ	Uzbekistan
FR	France	MN	Mongolia	VN	Viet Nam
GA	Gabon				

Medical Jet Injector for Administering Injections without a Needle

Technical Field

The present invention relates generally to a hypodermic injection apparatus, and more particularly to a medical jet injector for administering intramuscular and subcutaneous injections without a needle.

Background Art

Devices of this type have been known for a long time since a need exists for a relatively painless way to administer liquid medicinal substances percutaneously. It is well known that for example, persons afflicted with diabetes mellitus have a need to take one or more doses of insulin daily. The needless injection of medicines into the body is decidedly preferable to injection by means of skin piercing needles. However, needless injectors have only recently begun to achieve public acceptance.

Hungarian Patent Specification No. 207231 discloses a hypodermic injection device that includes an injection head comprising a centrally located longitudinal chamber capable of being filled with a determined dose of a liquid medicinal

substance and a piston guided to move inside said longitudinal chamber and intended both to fill said chamber with the predetermined dose of the medicinal substance and to expel the medicinal substance under high pressure when applied to the skin of a patient. The known injection device also includes at least one adapter assembly for temporary storing and penetrating a medicament vial. The adapter assembly is applicable to the injection head for filling the longitudinal chamber with the determined dose of the medicinal substance. The known hypodermic injection device further includes an injector power unit that has an energy storing compression spring and a releasable latch mechanism. The injector power unit comprises a ram that is slideably mounted in an inner barrel and is rigidly connected to the piston of the injection head for synchronous longitudinal movement in both directions. One end of the barrel and thus, the injector power unit is applicable by means of its male threaded end portion to the injection head. The barrel houses the energy storing compression spring between the ram and a slideably guided load bearing member, and the barrel also comprises a threaded driving bolt which bears, at one of its ends, against the load bearing member and is, at its other end, drivingly secured to a winding sleeve so that by rotating the winding sleeve the tension and thus, the energy stored in the compression spring is altered in accordance with the actual sense of rotation. The inner barrel of the injector power unit is slideably but non-rotatably mounted in a tubular body. The freedom of relative longitudinal stroke of the barrel against the body is limited to a displacement between two definite end positions, and the barrel is held in one of its end positions by means of a slightly pre-stressed return spring. An end portion of the tubular body is designed and shaped such that it is capable of slideably receiving a tubular head housing of the injection head. The end portion of the tubular body is provided with a leading edge which allows, in co-operation

with a proper graduation on the outer mantle surface of the tubular head housing of the injection head while the latter is rotated, for a visual indication of the dose of the liquid medicinal substance drawn up and contained in the centrally located longitudinal chamber of the injection head for the purpose of subsequent injection.

The releasable latch mechanism of the known hypodermic injection device comprises at least one locking ball that, in the normal state of the device when the longitudinally position of the ram is locked with respect to the barrel, protrudes at least partially, in an annular groove of the ram. The at least one locking ball is slideably fitted in at least one radial bore of the barrel and it is, again in the normal state of the device when the longitudinally position of the ram is locked against the barrel, prevented from its radially outward displacement by another ball which is held stationary by a pre-stressed return spring.

The known device has proved to be feasible from the point of view of both its operation and economy. Practical experience has shown, however, that cleaning and sterilisation of the known device cause problems to the users since it requires time consuming disassembling of the device which may put especially unexperienced and less technically minded users to some trouble. Thus, for the purpose of cleaning and maintenance, the device has to be given away to a professional service station rather frequently.

Another reason for the limited use of the known injector is the difficulties and inconvenience involved in injecting different patients using the same injector. Until now, it was necessary to sterilise an injector used to inject one patient before using the same injector for injecting another. The same problem appears when the need for injecting different medicines in success arises. In such

cases sterilisation is necessary to purge the contaminating first medicine. Accordingly, for the most part, the use of the known needless injector has been limited to situations, e.g. the administration of local anesthetics or insulin in which neither the type of medicine nor the patient is changed frequently.

From the above description of the background art it may be readily understood that a need exists for a device which permits the extension of needless injection to situations in which a variety of medicines are injected into successive patients.

The principal object of the invention is to provide an improved hypodermic injecting device by which the above mentioned need can be met.

It has been discovered that both from the functional point of view and also in view of their relation to users of the device, the known hypodermic devices consist of two basic assembly units.

One of these units is the injection head which contacts both the medicinal substance and the patient to be injected. During the administration of an injection, the fluid jet driven at high pressure through the patient's skin may result in some minor amount of bleeding and thus, there is a possibility that blood might flow back into the ejection orifice to contaminate the injection head. In order to avoid cross-contamination of blood between different patients being injected or between different medicinal substances being used in success, it would be necessary to disassemble the injection head and sterilise at least those portions of the same that could conceivably retain contaminated blood or remainings of medicinal substances used previously.
The second basic assembly unit is the power unit or thrust

mechanism that in fact, nearly never needs sterilisation. Although the structure of this unit is more complicate than that of the injection head, it can be designed and manufactured by using hitherto known techniques so as to be practically of no need of maintenance and repair.

Based on the above recognition, another object of the present invention is to provide an improved medical jet injector the injection head of which can easily be cleaned and sterilised even by patients not having sophisticated technical knowledge and experience.

Disclosure of the Invention

The above and other objects are achieved by the provision of an improved medical jet injector the injection head of which is, in accordance with the main characteristic feature of the present invention, designed and shaped so as to form a complete, interchangeable sub-assembly capable of being, especially for the purposes of cleaning, disinfection and/or other maintenance operations, separated as a whole from the injector power unit, while the injection head also comprises means for retaining the piston within the injection head while the latter is separated from the injector power unit. In order to facilitate further disassembling of the injection head for the purpose of more comprehensive sterilisation, the retaining means is releasable by means of an auxiliary release tool that is applicable to the injection head when the latter is detached from the injector power unit.

In preferred embodiments of the invention the auxiliary release tool used for releasing said means for retaining the piston within the injection head is preferably made of a suitable plastic material, and it comprises a female

threaded portion that can be screwed into a skirt portion of a tubular head housing of the injection head when the latter is detached from the injector power unit whereby a sleeve is displaced longitudinally along the mantle of a tubular inward projection of a cylinder sleeve against the force of a pre-compressed spring coil. This enables the radially outward displacement of retaining balls in result of which said balls can disengage from a cylindrical shaft portion of the piston that will allow for the piston to be removed from and replaced, after maintenance, again into the injection head.

The present invention is deemed to be an improvement over the prior art since its injection head is easily detachable from the injector power unit and it can even be replaced by another identical injection head that may have been cleaned and sterilised previously at another location, if necessary. For doing so, it is no more necessary for the injector power unit to be disassembled. This has been made possible by having made the piston actuating ram of the injector power unit detachable from the piston. Similarly to the hitherto known device, the said ram is retained stationary in the barrel of the injector power unit by means of a releasable latch mechanism. In order to eliminate the possibility of the ram being accidentally "fired" through the open mouth portion of the barrel when the injecting head is detached from the injector power unit and the compression spring of the same is in its energy storing pre-compressed state which might cause serious damage and injury, the injector power unit comprises a tension spring by which the ram is connected to a load bearing member. In a preferred embodiment the tension spring is arranged within the energy storing compression spring.

According to practical experience the pain felt at the moment of injection can be considerably reduced and the

damage to the skin of the patient is avoided if the orifice of the injection unit used for needleless injection comprises a plurality of very fine holes through which the medicinal substance is ejected. In preferred embodiments of the medical jet injector according to the present invention the mouthpiece of the injection head comprises a plurality of small injection holes. In addition to this, the mouthpiece is designed and shaped so that it can be attached, by providing a sealed connection, to a male threaded protruding portion of the cylinder sleeve of the tubular head housing of the injection head when administering the injection. The mouthpiece is detachable and interchangeable against the adapter assembly for filling the centrally located longitudinal chamber of the injection head with the determined dose of the medicinal substance from a medicament vial.

In preferred embodiments of the present invention the inner barrel of the injector power unit is slidably but non--rotatably mounted in a tubular body, and one end portion of the tubular body is designed and shaped such that it is capable of slideably receiving the skirt portion of the tubular head housing of the injection head. The end portion of the tubular body is provided with a leading edge which allows, in co-operation with a proper graduation on the outer mantle surface of the skirt portion of the tubular head housing of the injection head while the latter is rotated, for a visual indication of the dose of the liquid medicinal substance drawn up and contained in the centrally located longitudinal chamber of the injection head for the purpose of subsequent injection.

In order to enable patients with visual impairs or even blind patients to make use of the device of the present invention, in preferred embodiments of the improved medical jet injector the outer mantle surface of the skirt portion

of the tubular head housing of the injection head is provided with circumsferentially spaced longitudinal recesses, and the medical jet injector comprises an acoustic device for indicating, especially to persons who are blind or have visual impairs, the dose of the liquid medicinal substance drawn up and contained in the centrally located longitudinal chamber of the injection head. The acoustic device is provided by a ball that is slideably mounted for radial movement, together with a spring in a socket fitted in a radial bore of the end portion of the tubular body of the injector power unit. The ball is forced, by means of the pre-stressed, preferably rubber spring against the outer mantle surface of the tubular head housing and the device is capable of generating, in co-operation with the longitudinal recesses, acoustic signals while the tubular head housing of the injection head is rotated relative to the tubular body of the injector power unit for the purpose of drawing up the predetermined dose of liquid medicinal substance to be injected.

Brief Description of the Drawings

The invention will now be described in greater detail with reference to the accompanying drawings, which illustrate, by way of example only, a preferred embodiment of the invention, and wherein:

Fig. 1 is a longitudinal sectional view of one embodiment of the medical jet injector of the present invention;

Fig. 2 is a schematic side elevation view of the injection head of the jet injector;

Fig. 3 is a schematic longitudinal sectional view of the injection head shown in Fig. 2;

Fig. 4 is an "exploded" side elevation view showing

the main component parts of the injection head of the medical jet injector;

Fig. 5 is a side elevation view showing the front end of the injector head of the jet injector only,

Fig. 6 is another side elevation view of the front end of the injection unit illustrating the adapter assembly attached thereto, together with a medicament vial;

Fig. 7 is a side elevational view of the tubular head housing of the injection unit of the medical jet injector of the invention, and

Fig. 8 is a schematic rear end view of the tubular head housing illustrating, by way of example only, the graduation for visually indicating the dose of medicinal substance drawn up in the injector head of the medical jet injector of the invention.

Description of the Preferred Embodiment

The preferred embodiment of the medical jet injector of the invention includes, as it can be seen from the attached drawing figures, an injection head 1 comprising a centrally located longitudinal chamber 14 capable of being filled with a predetermined dose of a liquid medicinal substance, and a piston 15 guided to move inside said longitudinal chamber 14 and intended both to fill said chamber 14 with the predetermined dose of the medicinal substance and to expel said substance through fine holes of a mouthpiece 10 of said injection head 1 when applied to the skin of a patient. As shown in Fig. 6 of the attached drawings, the medical jet injector also includes at least one adapter assembly 6 for temporary storing and penetrating a medicament vial 7. The adapter assembly 6 is applicable to the injection head 1 for filling the longitudinal chamber 14 with the determined dose of the medicinal substance. The medical jet injector further

includes an injector power unit 2 that has an energy storing compression spring 25 and a releasable spring compression latch mechanism 4. The injector power unit 2 comprises a ram 21 that is slideably mounted in an inner barrel 20 and is, in normal operation of the medical jet injector, connected to the piston 15 of the injection head 1 for synchronous longitudinal movement in both directions. One end of said barrel 20 is applicable by means of its male threaded end portion, to the injection head 1. The barrel 20 houses the energy storing compression spring 25 in a space between the ram 21 and a slideably guided load bearing member 22, and the barrel 20 also comprises a threaded driving bolt 23 which bears, at one of its ends, against the load bearing member 22. The driving bolt 23 is, at its other end, drivingly secured to a winding sleeve 28 so that by rotating the winding sleeve 28 the tension and thus, the energy stored in the compression spring 25 is altered in accordance with the actual sense of rotation. In accordance with one of the important features of the invention, the injection head 1 of the medical jet injector is designed and shaped so that it forms a complete, interchangeable sub-assembly capable of being, especially for the purposes of cleaning, disinfection and/or other maintenance operations, separated as a whole from the injector power unit 2. The injection head 1 also comprises a means for retaining the piston 15 within the injection head 1 while the latter is separated from the injector power unit 2. The piston retaining means is releasable by means of an auxiliary release tool 5 that is applicable to the injection head 1 when the latter is detached from the injector power unit 2 as it is illustrated clearly in Figs. 3 and 4 of the drawings.

The injection head 1 of the medical jet injector includes a tubular head housing 11 comprising a female threaded skirt portion 111 and a central longitudinal bore in which a cylinder sleeve 12 having a tubular inward projection 121

with longitudinally extending slots 122 is, preferably by means of shrinkage fit, rigidly secured. The cylinder sleeve 12 comprises in its end portion opposite to said inward projection 121 a plug 13 that has a conical inner wall portion and a central longitudinal communication bore through which the medicinal substance can be drawn up and expelled from the longitudinal chamber 14 of said injection head 1 during operation. The piston 15 of the injection head 1 has a conical tip portion 151 the tip of which is correspondingly shaped to the conical inner wall portion of said plug 13. The piston 15 further comprises a cylindrical base portion 152 having annular grooves for receiving elastomeric O-rings 16 so that the base portion 152 of the piston 15 is slideably and sealingly mounted within the cylinder sleeve 12 of the injection head 1. The piston 15 further comprises a cylindrical shaft portion 153 of reduced diameter, an annular abutting collar 154 of larger diameter, and a cylindrical end portion 155 that has an annular groove 156. The means for retaining the piston 15 within the injection head 1 of the medical jet injector comprises retaining balls 17 located in the longitudinally extending slots 122 of the tubular inward projection 121 of the cylinder sleeve 12. The retaining balls 17 are pressed by force of a spring coil 18 against the annular abutting collar 154 of the piston 15 via a sleeve 19 that is slideably mounted around the tubular inward projection 121 of the cylinder sleeve 12 in a space between the latter and the skirt portion 111 of the tubular head housing 11.

The auxiliary release tool 5 used for releasing the means for retaining the piston 15 within the injection head 1 is made of a suitable plastic material, and it comprises a female threaded portion capable of being screwed into the skirt portion 111 of the tubular head housing 11 of the injection head 1 when the latter is detached from the injector power unit 2 as it is clearly shown in Fig. 3 of

the attached drawings. By screwing the auxiliary release tool 5 into the skirt portion 111 of the tubular head housing 11 the sleeve 19 is displaced longitudinally along the mantle of the tubular inward projection 121 of the cylinder sleeve 12 against the force of the pre-compressed spring coil 18 whereby the radially outward movement of the retaining balls 17 is allowed. This results in that the disengagement of the balls 17 from the cylindrical shaft portion 153 of the piston 15 becomes possible, and this will allow for the piston 15 to be removed from and replaced, after maintenance, again into the injection head 1.

For ensuring the easy detachability of the injection head 1 from the injector power unit 2, the ram 21 of the latter is detachably connected to the end portion 155 of the piston 15 of the injection head 1, and in the normally locked state of the latch mechanism 4 the ram 21 is retained stationary relative to the barrel 20. The detachable connection between the ram 21 and the end portion 155 of the piston 15 is provided by at least one ball 3 that protrudes into the annular groove 156 of the end portion 155 of the piston 15. The ball 3 is arranged in a radial bore in a skirt 212 of the ram 21, and the ball 3 is, in normal operation of the medical jet injector, prevented from its radial outward movement by the inner mantle surface of the barrel 20. An open end mouth portion 201 of the barrel 20 is, however, made wide enough by having an enlarged inner diameter so that is allows a substantial radial outward displacement of the at least one ball 3 while the injection head 1 is detached from the power unit 2 by unscrewing its tubular head housing 11 from the barrel 20.

The injector power unit 2 of the medical jet injector of the invention also comprises a tension spring 26 by which the ram 21 is connected to the load bearing member 22 whereby an accidental "firing" of the ram 21 from the barrel 20 in the

energy storing compressed state of the compression spring 25 is prevented. This is especially important because due to this, the danger of injury caused by said accidental "firing" of the ram 21 in the detached state of the injector power unit 2 is entirely eliminated. In the preferred embodiment shown in the drawings the tension spring 26 is arranged inside the energy storing compression spring 25.

The power unit 2 of the jet injector according to the present invention also comprises a support ball 24 that is arranged between the threaded driving bolt 23 and the load bearing member 22 for providing reduced friction between these components parts during their relative rotation.

The mouthpiece 10 of the injection head 1 comprises a plurality of small injection holes (not shown in detail) and it is designed and shaped so that it can be attached, by providing a sealed connection, to a male threaded protruding portion of the cylinder sleeve 12 of the tubular head housing 11 of the injection head 1 (as shown in Fig. 5) when administering injection to the patient . The mouthpiece 10 is detachable and interchangeable against the adapter assembly 6 (see Fig. 6), for filling the centrally located longitudinal chamber 14 of the injection head 1 with the determined dose of the medicinal substance from the medicament vial 7.

The inner barrel 20 of the injector power unit 2 is slidably but non-rotatably mounted in a tubular body 27. Its freedom of relative longitudinal stroke movement with respect to the tubular body 27 is limited between two definite end positions, and the barrel 20 is normally held in one of its end positions by means of a slightly pre--stressed return spring 42. An end portion 271 of the tubular body 27 is designed end shaped such that it is capable of slideably receiving the skirt portion 111 of the

tubular head housing 11 of the injection head 1, and the end portion 271 of the tubular body 27 is provided with a leading edge 272 which allows, in co-operation with a proper graduation 112 on the outer mantle surface of the skirt portion 111 of the tubular head housing 11 of the injection head 1 (Figs. 7 and 8) while the latter is rotated, for a visual indication of the dose of the liquid medicinal substance drawn up and contained in the centrally located longitudinal chamber 14 of the injection head 1 for the purpose of subsequent injection. In order to ensure that the improved medical jet injector of the invention be also usable by patients having visual impairs or being even blind, the outer mantle surface of the skirt portion 111 of the tubular head housing 11 of the injection head 1 is provided with circumsferentially spaced longitudinal recesses 113, and the medical jet injector comprises an acoustic device 8 for indicating the dose of the liquid medicinal substance drawn up and contained in the centrally located longitudinal chamber 14 of the injection head 1. The acoustic device 8 comprises a ball 80 that is slideably mounted for radial movement, against a spring 81 in a socket 82 fitted in a radial bore of the end portion 272 of the tubular body 27 of the injector power unit 2. The ball 80 is forced, by means of the pre-stressed rubber spring 81, against the outer mantle surface of the tubular head housing 11 and the device is capable of generating, in co-operation with the longitudinal recesses 113, acoustic signals while the tubular head housing 11 of the injection head 1 is rotated relative to the tubular body 27 of the injector power unit 2 for the purpose of drawing up the pre-determined dose of liquid medicinal substance to be injected.

The releasable latch mechanism 4 of the medical jet injector of the invention comprises locking balls 40 which, in the normal, locked state of the device when the longitudinally

position of the ram 21 relative to the barrel 20 is locked, protrude in an annular groove 211 of the ram 21. The locking balls 40 are slidably fitted in circumsferentially spaced radial bores of the barrel 20 and they are, again in the normal state of the medical jet injector when the longitudinally position of the ram 21 is locked relative to the barrel 20, prevented from their radially outward displacement by spherical inward projections 41 that are secured to the tubular body 27. The locking balls 40 and the spherical inward projections are held in their longitudinal relative positions facing each other by the slightly pre-stressed coiled return spring 42.

Operation

When the injection head 1 of the medical jet injector is attached to the injector power unit 2 as shown in Fig. 1 of the attached drawings, the winding sleeve 28 will first be turned anti-clockwise with respect to the tubular body 27 until a mechanical stop (not shown) is reached. The anti--clockwise rotation of the winding sleeve 28 functions to decompress the compression spring 25 through the threaded driving bolt 23 the forward end of which bears against the rear surface of the load bearing member 22. The winding torque is reduced (in both senses of rotation) by the support ball 24. Following this, the tubular head housing 11 of the injection unit 1 is turned clockwise. The number of rotations needed will vary in accordance with the previous injection dosage. This results in that the piston 15 moves forward into the centrally located longitudinal chamber 14 until its conical tip portion abuts against the correspondingly shaped conical inner wall portion of the plug 13 whereby the air contained in the chamber 14 previously will be entirely expelled therefrom. Having reached this state, the tubular head housing 11 will stop

at a position with respect to the tubular body 27 where the "0" reading of the graduation 112 can be observed at the leading edge 272 of the tubular body 27, indicating that a zero volume dosage is contained in the chamber 14. The releasable latch mechanism 4 is in its normal, locked state as shown in Fig. 1. The locking balls 40 are in facing relationship to the spherical inward projections 41 both radially and longitudinally, and they are held in their locking position in which they partially protrude in the annular groove 211 of the ram 21. Thus, the ram 21 and the piston 15 connected thereto are securely held in their locked positions with respect to the inner barrel 20. As a next step of operation the mouthpiece 10 is unscrewed and exchanged against the adapter assembly 6 (see Fig. 6) that contains the medicament vial 7 the rubber lid of which is penetrated by a hollow needle 62. A base portion 61 of the adapter assembly is designed and shaped in a manner that it provides for an airtightly sealing fit between the male threaded forward portion of the cylinder sleeve 12 and the interior of the medicament vial 7. The tubular head housing 11 of the injection head 1 will then be turned anti--clockwise with respect to the tubular body 27 of the injector power unit 2 until the predetermined dose of the medicinal substance is drawn up in the longitudinal chamber 14 of the injection head 1 through the central communication bore in the plug 13 which bore is in communicating alignment with the longitudinal bore of the needle 62. Filling the chamber 14 with the medicinal substance is effected by causing to move the piston 15 outwardly from the chamber 14 through the anti-clockwise rotation of the tubular head housing 11 relative to the tubular body 27 in which the inner barrel 20 (the male threaded forward end portion of which is in engagement with the female threaded skirt portion 111 of the head housing 11) is slideably but non--rotatably mounted via a key 29. The prescribed dose of the medicinal substance to be injected will determine the number

of rotations, and the current amount of medicinal substance drawn up in the chamber 14 of the injection head 1 is visually indicated by the particular reading that just appears visible at the leading edge 272 of the tubular body 27. In addition to this indication, acoustic signals indicating the dosage drawn up in the chamber 14 are also generated by the ball 80 of the acoustic device 8 of the medical jet injector of the invention. The ball 80 is forced by the rubber spring 81 towards the outer mantle surface of the tubular head housing 11, and it generates discrete clicks when crossing the longitudinal recesses 113 of the latter upon rotation. By counting the number of such clicks, patients having some experience in handling the medical jet injector may obtain sufficient information on the dosage drawn up even if they are blind or suffer of visual impairs. Drawing up the medicinal substance can be interrupted at any time, and by exchanging the adapter assembly 6 against another such assembly housing a medicament vial (7) which contains a medicinal substance that is different but mixable with the one drawn up previously, the medical jet injector of the invention allows for the administration of injections of predetermined doses of mixtures of different but mixable medicinal substances to patients. Air that may have been drawn up accidentally in the chamber 14 can be expelled therefrom before injection by turning the device in a vertical position where the medicament vial 7 in the adapter assembly 6 is turned upright, and by a subsequent slight clockwise rotating the tubular head housing 11, if necessary.

Once the correct dosage amount of the medicinal substance or mixture of such substances is loaded into the chamber 14 of the injection head 1, the adapter assembly 6 is detached from the latter, and it is exchanged against the mouthpiece 10 by airtightly securing the latter to the male threaded protruding portion of the cylinder sleeve 12 of the

injection head 1.

Following this, the winding sleeve 28 of the injector power unit 2 is turned clockwise with respect to the tubular body 27 whereby the load bearing member 22 is moved via the threaded driving bolt 23 and the support ball 24 in a direction towards the ram 21, and the compression spring 25 is loaded by compression. The actual load in the compression spring 25 will vary in accordance with the number of rotations. Recommended stages of load can be indicated by markings on the outer mantle surface of the winding sleeve 28. Since the ejection intensity of the medicinal substance through the fine holes of the orifice of the mouthpiece 10 of the injection head 1 and thus, the penetration of the substance injected through the patient's skin into the body tissue is largely determined by the load applied to and stored temporary in the compression spring 25, it is readily apparent that the medical jet injector of the invention is capable of administering injections of different and properly predetermined intensity to patients.

Having concluded the above described operational steps the medical jet injector of the invention is ready for performing the injection. The injection is administered by pressing the mouthpiece 10 against the skin of the patient while the injector is held in a substantially perpendicular orientation to the body section to be injected. The injector is gripped by the tubular body 27 of the injector power unit 2, and a sudden additional pressure impact is exerted against the body portion to be injected. This will result in a short longitudinal relative stroke displacement of the tubular body 27 with respect to the inner barrel 20 that is connected to the injection head 1, causing the equal longitudinal relative movement of the spherical inward projections 41 with respect of the locking balls 40. Thus, the locking balls 40 are allowed to move in radial outward

direction, and the locking balls 40 will, forced by the compression spring 25, disengage from the annular groove 211 of the ram 21 whereby the latch mechanism 4 is unlocked and the ram 21 is allowed, together with the piston 15, to rapid forward movement towards the mouthpiece 10 of the injector developing a high penetration pressure generated by the load stored in the compression spring 25.

After injection, the above described operational steps are to be performed in the same sequence in order to prepare the medical jet injector for performing a subsequent injection. As the injection head 1 is brought, by rotating the tubular head housing 11 of the injection head 1, again to its zero chamber volume position in which the "0" reading of the graduation 112 faces the leading edge 272 of the tubular body 27, the ram 21 will return in its normally locked longitudinal position with respect to the inner barrel 20. As the annular groove 211 arrives at its position where it is in radial alignment with the radial bores in the skirt 212 of the barrel 20 in which the locking balls 40 are seated for radial displacement, the locking balls 40 are pressed back, by force of the slightly pre-stressed return spring 42, into their engagement with the groove 211 of the ram 21, and they are held in their locked position by the simultaneously returning spherical inward projections 41 until subsequent injection is initiated.

According to one of the main characteristic features of the present invention the injection head 1 is designed and shaped so that it provides a complete, interchangeable sub--assembly capable of being, especially for the purposes of cleaning, disinfection and/or other maintenance operations, separated as a whole from the injector power unit 2. For separating the injection head 1 from the injector power unit 2 the tubular head housing 11 is turned anti-clockwise whereby it can be fully disengaged from the male threaded

forward end of the inner barrel 20. As, during rotation, the at least one ball 3 arrives the area of the mouth portion 201 of enlarged inside diameter of the barrel 20, it becomes free to move radial outwardly so that it is no more retained in the annular groove 156 of the piston 15. Thus, the normally retained engagement between the end portion 155 of the piston 15 and the ram 21 of the injector power unit 2 is released, and the injection head 1, together with the piston 15 retained therein, can be pulled out from the tubular body 27 and thus, separated from the injector power unit 2. Since the ram 21 remains still connected, via the tension spring 26, to the load bearing member 22, the accidental "firing" of the same through the open mouth portion 201 of the barrel 20 from the detached injector power unit 2 that might cause serious damage and injuries if the compression spring 25 were "loaded", is prevented entirely.

In its stage detached from the injector power unit 2, the injection head 1 can be cleaned and sterilised very easily. Sterilisation can be achieved e.g. by simple cooking in boiling water, though other more sophisticated techniques of sterilisation are applicable, too. In certain applications a partway sterilisation of at least certain component parts of the injection head 1 may become necessary. For that purpose the injection head 1 can be easily disassembled in its components shown in Fig. 4 of the attached drawings. For doing so, the auxiliary release tool 5 having a male threaded mantle portion capable of being brought in engagement with the female threaded skirt portion 111 of the tubular head housing 11 is applied to the latter by inserting and screwing it into the skirt portion 111 of the tubular head housing 11 of the injection head 1 while the latter is detached from the injector power unit 2 as shown in Fig 3. of the attached drawings. After the leading edge of the auxiliary release tool 5 abuts the end of the sleeve

19, upon further clockwise rotation of the auxiliary release tool 5 the sleeve 19 will be slid longitudinally on the outer mantle surface of the tubular inward projection 121 of the cylinder sleeve 12 against the force of the pre--compressed spring coil 18 whereby the displacement of the retaining balls 17 in radial outward direction becomes possible. The normally retained engagement between the piston 15 and the cylinder sleeve 12 is herewith released, and the piston 15 can also be separated from the injection head 1. The longitudinal chamber 14 and the piston 15, together with all other component parts and hidden spaces of the injection head 1 can now be cleaned and sterilised very easily and with high efficiency. Cleaning, sterilisation, maintenance and repair of the injection head 1 can be performed even independently from the injector power unit 2 at different locations while the injector power unit 2 may be further in continuous use associated with another injection head 1 out of a number of such interchangeable units. Reassembling of the cleaned, sterilised or repaired injection unit 1 is effected by performing the steps as described above in reverse order.

Claims

1. A medical jet injector for administering intramuscular and subcutaneous injections without a needle, said jet injector including an injection head (1) comprising a centrally located longitudinal chamber (14) capable of being filled with a determined dose of a liquid medicinal substance and a piston (15) guided to move inside said longitudinal chamber (14) and intended both to fill said chamber with the predetermined dose of the medicinal substance and to expel said substance through fine holes of a mouthpiece (10) of said injection head (1) when applied to the skin of a patient, the medical jet injector also including at least one adapter assembly (6) for temporary storing and penetrating a medicament vial (7), said adapter assembly (6) being applicable to said injection head (1) for filling the longitudinal chamber (14) with the determined dose of the medicinal substance, said medical jet injector further including an injector power unit (2) having an energy storing compression spring (25) and a releasable spring compression latch mechanism (4), said injector power unit (2) comprising a ram (21) that is slideably mounted in an inner barrel (20) and is, in normal operation of the medical jet injector, connected to the piston (15) of the injection head (1) for synchronous longitudinal movement in both directions, one end of said barrel (20) being applicable by means of its male threaded end portion, to said injection head (1), said barrel (20) comprising said energy storing compression spring (25) between said ram (21) and a slideably guided load bearing member (22), and the barrel (20) also comprising a threaded driving bolt (23) which bears, at one of its ends, against said load bearing

member (22) and is, at its other end, drivingly secured to a winding sleeve (28) so that by rotating said winding sleeve (28) the tension and thus, the energy stored in said compression spring (25) is altered in accordance with the actual sense of rotation, the medical jet injector being characterised in said injection head (1) being designed and shaped so as to form a complete, interchangeable sub--assembly capable of being, especially for the purposes of cleaning, disinfection and/or other maintenance operations, separated as a whole from said injector power unit (2), and said injection head (1) also comprising a means for retaining the piston (15) within said injection head (1) while the latter is separated from the injector power unit (2), said piston retaining means being releasable by means of an auxiliary release tool (5) that is applicable to said injection head (1) when the latter is detached from said injector power unit (2).

2. The improved medical jet injector as claimed in Claim 1, characterised in said injection head (1) including a tubular head housing (11) comprising a female threaded skirt portion (111) and a central longitudinal bore in which a cylinder sleeve (12) having a tubular inward projection (121) with longitudinally extending slots (122) is, preferably by means of shrinkage fit, rigidly secured, said cylinder sleeve (12) comprising in its end portion opposite to said inward projection (121) a plug (13) having a conical inner wall portion and a central longitudinal communication bore through which the medicinal substance can be drawn up and expelled from the longitudinal chamber (14) of said injection head (1) during operation, and the piston (15) of said injection head (1) comprising a conical tip portion (151) the tip of which is shaped so as to correspond to the conical inner wall portion of said plug (13), said piston (15) further comprising a cylindrical base portion (152) having annular grooves for receiving elastomeric O-rings

(16) so that said base portion (152) of said piston (15) is slideably and sealingly mounted within said cylinder sleeve (12) of said injection head (1), and the piston (15) further comprising a cylindrical shaft portion (153) of reduced diameter, an annular abutting collar (154) of larger diameter, and a cylindrical end portion (155) having an annular groove (156) therein; said medical jet injector being further characterised in said means for retaining the piston (15) within the injection head (1) comprising retaining balls (17) located within the longitudinally extending slots (122) of said tubular inward projection (121) of said cylinder sleeve (12), said retaining balls (17) being pressed by force of a spring coil (18) against said annular abutting collar (154) of said piston (15) via a sleeve (19) that is slideably mounted around the tubular inward projection (121) of said cylinder sleeve (12) in a space between the latter and the skirt portion (111) of said tubular head housing (11).

3. The medical jet injector as claimed in Claim 1 or 2, characterised in said auxiliary release tool (5) used for releasing said means for retaining the piston (15) within said injection head (1) being preferably made of a suitable plastic material and comprising a female threaded portion capable of being screwed into the skirt portion (111) of the tubular head housing (11) of the injection head (1) when the latter is detached from the injector power unit (2), whereby the sleeve (19) is displaced longitudinally along the mantle of the tubular inward projection (121) of the cylinder sleeve (12) against the force of the pre-compressed spring coil (18) whereby the radially outward movement of the retaining balls (17) is allowed and in result of which the disengagement of said balls (17) from the cylindrical shaft portion (153) of the piston (15) will allow for the piston (15) to be removed from and replaced, after maintenance, again into said injection head (1).

4. The medical jet injector as claimed in one of the Claims 2 to 3, characterised in said ram (21) of said injector power unit (2) being detachably connected to said end portion (155) of said piston (15) of the injection head (1), and said ram (21) being retained stationary in said barrel (20) by means of a releasable latch mechanism (4).

5. The medical jet injector as claimed in Claim 4, characterised in said detachable connection between said ram (21) and said end portion (155) of said piston (15) being provided by at least one ball (3) that protrudes, at least partially, into the annular groove (156) of said end portion (155) of the piston (15), said at least one ball (3) being arranged in at least one radial bore in a skirt (212) of the ram (21), the at least one ball (3) being, in normal operation of the medical jet injector, prevented from radial outward movement by the inner mantle surface of said barrel (20) an open end mouth portion (201) of which being wide enough by having an enlarged inner diameter so as to allow for a substantial radial outward displacement of the at least one ball (3) while the injection head (1) is detached from the power unit (2) by unscrewing its tubular head housing (11) from the barrel (20).

6. The medical jet injector as claimed in any of the preceding Claims 1 to 5, characterised in further comprising a tension spring (26) by which the ram (21) of the injector power unit (2) is connected to the load bearing member (22), said tension spring (26) being preferably arranged inside the energy storing compression spring (25).

7. The medical jet injector as claimed in any of the preceding Claims 1 to 6, characterised in further having a support ball (24) that is arranged between the threaded driving bolt (23) and the load bearing member (22) for providing reduced friction between said components parts

during their relative rotation.

8. The medical jet injector as claimed in any of the preceding claims 1 to 7, characterised in said mouthpiece (10) of the injection head (1) comprising a plurality of small injection holes and being designed and shaped so that it can be attached, by providing a sealed connection, to a male threaded protruding portion of the cylinder sleeve (12) of the tubular head housing (11) of the injection head (1) when performing injection, said mouthpiece (10) being detachable and exchangeable against the adapter assembly (6) for filling the centrally located longitudinal chamber (14) of the injection head (1) with the determined dose of the medicinal substance from the medicament vial (7).

9. The medical jet injector as claimed in any of the preceding Claims 1 to 8, characterised in said inner barrel (20) of the injector power unit (2) being slidably but non--rotatably mounted in a tubular body (27), its freedom of relative longitudinal stroke movement against said tubular body (27) being limited between two definite end positions, the barrel (20) being normally held in one of its end positions by means of a slightly pre-stressed return spring (42), an end portion (271) of the tubular body (27) being designed and shaped such as to be capable of slideably receiving the skirt portion (111) of the tubular head housing (11) of the injection head (1), and said end portion (271) of said tubular body (27) being provided with a leading edge (272) which allows, in co-operation with a graduation (112) on the outer mantle surface of the skirt portion (111) of the tubular head housing (11) of the injection head (1) while the latter is rotated, for a visual indication of the dose of the liquid medicinal substance drawn up and contained in the centrally located longitudinal chamber (14) of the injection head (1) for the purpose of subsequent injection.

10. The medical jet injector as claimed in Claim 9, characterised in said outer mantle surface of the skirt portion (111) of the tubular head housing (11) of the injection head (1) being provided with circumsferentially spaced longitudinal recesses (113), and the medical jet injector further comprising an acoustic device (8) for indicating the dose of the liquid medicinal substance drawn up and contained in the centrally located longitudinal chamber (14) of the injection head (1), said acoustic device (8) comprising a ball (80) that is slideably mounted for radial movement against a spring (81) in a socket (82) fitted in a radial bore of the end portion (272) of the tubular body (27) of the injector power unit (2), said ball (80) being forced, by means of the pre-stressed, preferably rubber spring (80) against said outer mantle surface of the tubular head housing (11), said acoustic device (8) being capable of generating, in co-operation with said longitudinal recesses (113), acoustic signals while said tubular head housing (11) of the injection head (1) is rotated relative to the tubular body (27) of the injector power unit (2) for the purpose of drawing up the predetermined dose of liquid medicinal substance to be injected.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/HU 94/00058

Im Recherchenbericht angeführtes Patentdokument Patent document cited in search report Document de brevet cité dans le rapport de recherche	Datum der Veröffentlichung Publication date Date de publication	Mitglied(er) der Patentfamilie Patent family member(s) Membre(s) de la famille de brevets	Datum der Veröffentlichung Publication date Date de publication
US A 5062830	05-11-91	keine - none - rien	
EP A1 406778	09-01-91	HU B 200699	28-08-90
		IL A0 94704	15-04-91
CA A 1258019		keine - none - rien	
US A 5074843	24-12-91	AT E 92347	15-08-93
		AU A1 45235/89	28-05-90
		AU B2 628423	17-09-92
		BR A 8907143	13-02-91
		CA AA 2002102	03-05-90
		DE C0 68908084	09-09-93
		DE T2 68908084	14-04-94
		EP A1 367677	09-05-90
		EP B1 367677	04-08-93
		FR A1 2638360	04-05-90
		JP T2 3503968	05-09-91
		WO A1 9004989	17-05-90

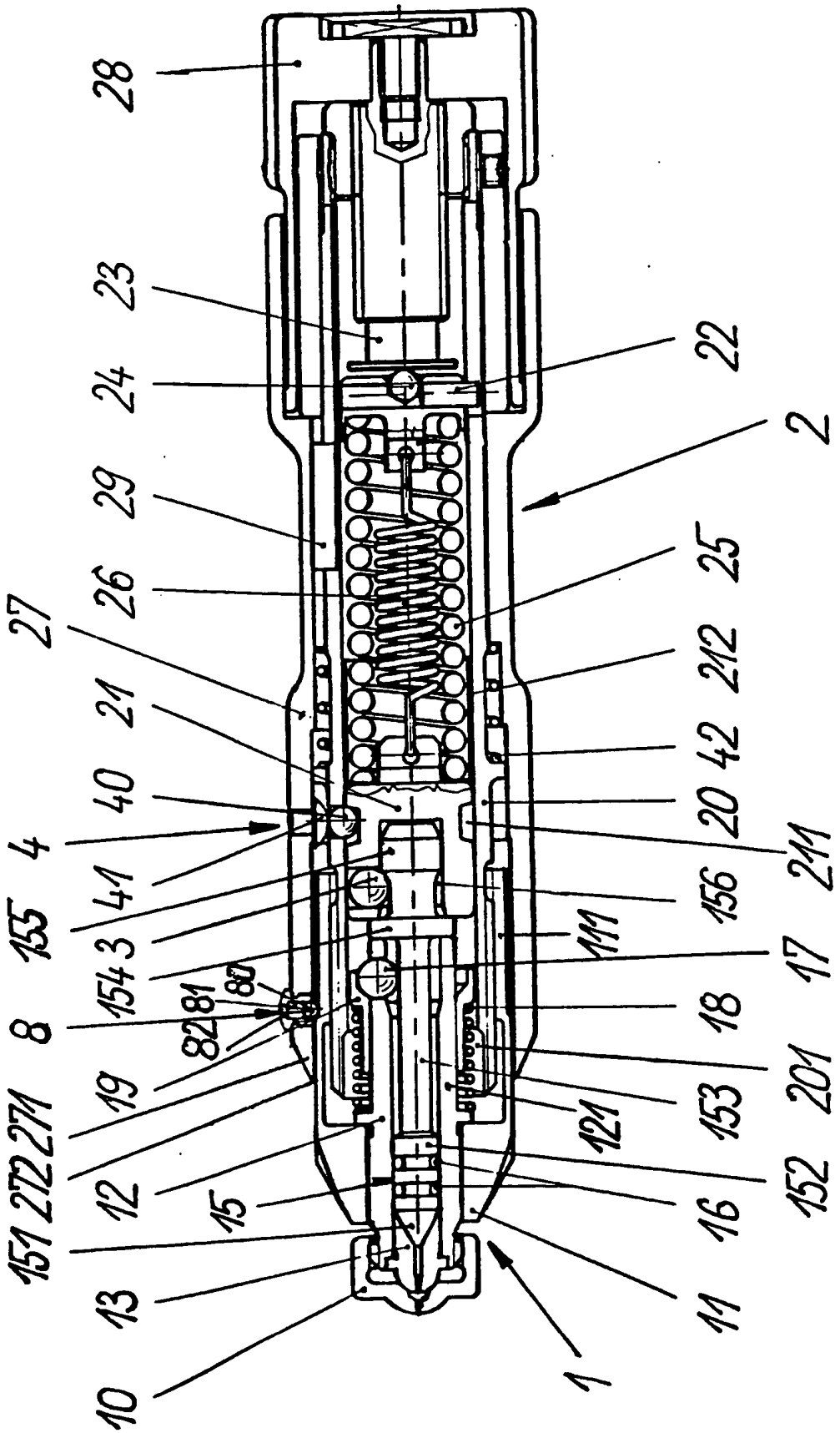

28
23
24
29
26
27
21
40
4
41
155
3
154
8
82
81
80
19
271
272
151
12
15
13
10
1
11
16
152
153
121
201
18
17
111
156
211
20
42
212
25
22
2

Fig. 1

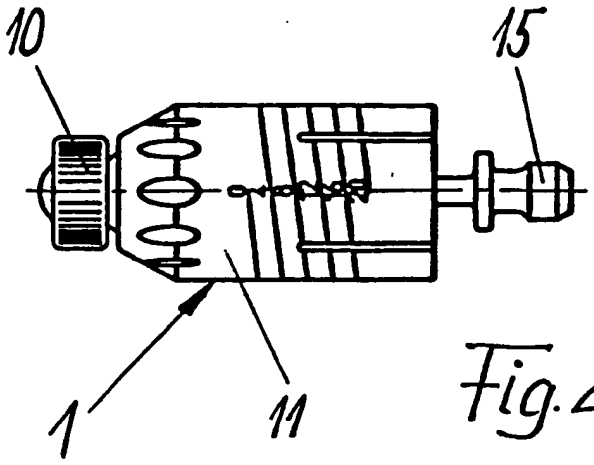


Fig. 2

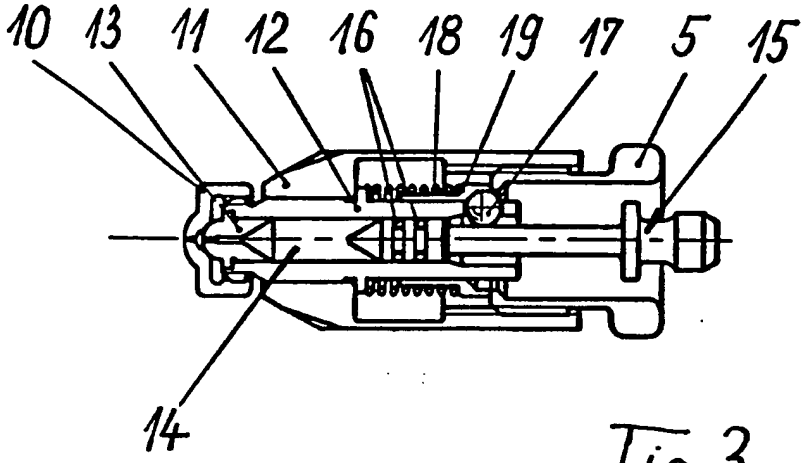


Fig. 3

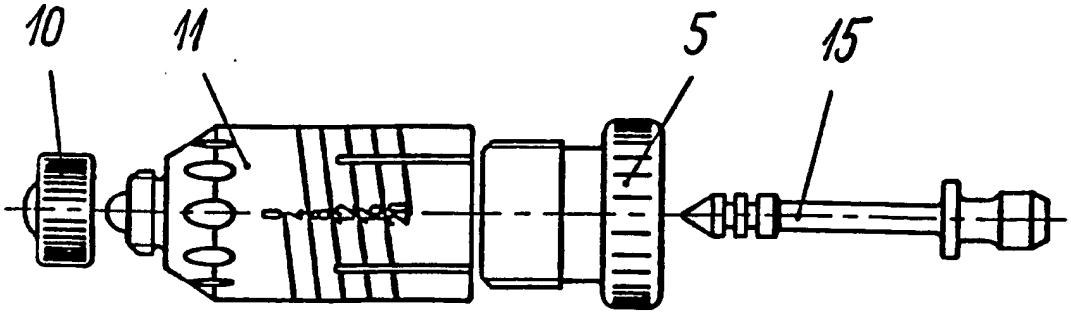


Fig. 4

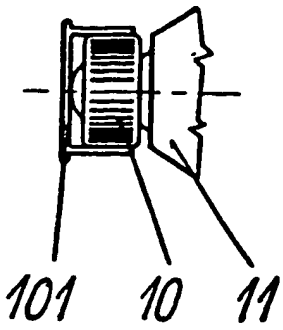


Fig. 5

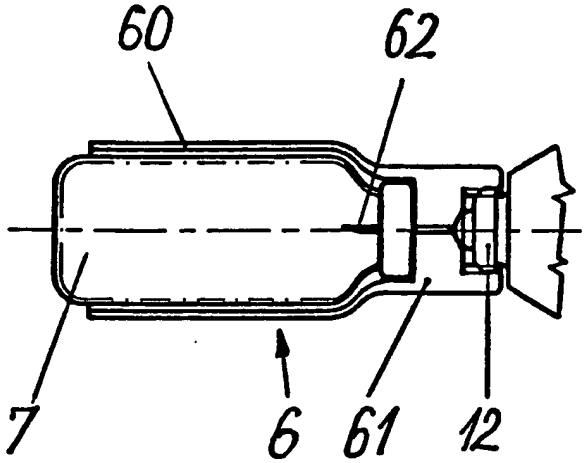


Fig. 6

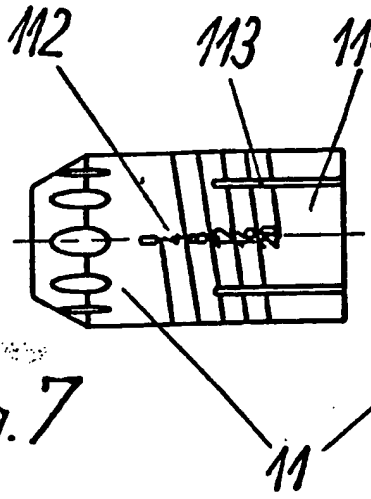


Fig. 7

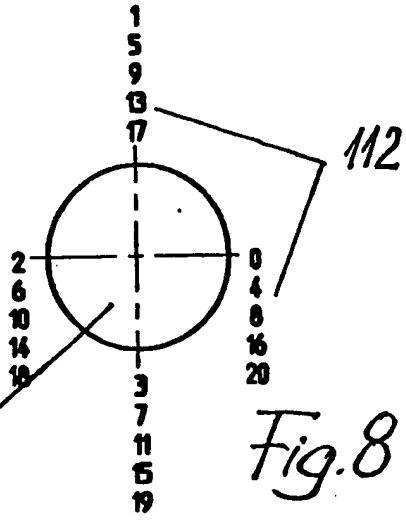


Fig. 8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/HU 94/00058

A. CLASSIFICATION OF SUBJECT MATTER

IPC[6]: A 61 M 5/30

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC[6]: A 61 M 5/30

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

-

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

-

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 062 830 A (K.W.DUNLAP) 05 November 1991 (05.11.91), fig. 1-4; column 3, line 67 - column 7, line 38.	1
A	EP 0 406 778 A1 (E.GYULA et al.) 09 January 1991 (09.01.91), fig. 1,5; column 4, line 4 - column 5, line 31.	1
A	CA 1 258 019 A (I. LINDMAYER) 01 August 1989 (01.08.89), fig. 1-9; page 4, line 5 - page 7, line 28.	1
A	US 5 074 843 A (T. DALTO et al.) 24 December 1991 (24.12.91), fig. 3; abstract.	8

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
12 April 1995 (12.04.95)	02 May 1995 (02.05.95)
Name and mailing address of the ISA/ AT AUSTRIAN PATENT OFFICE Kohlmarkt 8-10 A-1014 Vienna Facsimile No. 1/53424/535	Authorized officer Ludwig e.h. Telephone No. 1/53424/349

Form PCT/ISA/210 (second sheet) (July 1992)